



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0237 and EPA-HQ-OPPT-2019-0238; FRL-9995-40]

Draft Toxic Substances Control Act (TSCA) Risk Evaluations and TSCA Science Advisory Committee on Chemicals (SACC) Meetings; Cyclic Aliphatic Bromide Cluster (HBCD) and 1,4-Dioxane; Notice of Availability and Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA announces the availability of documents and dates for the peer review of the draft risk evaluations for Cyclic Aliphatic Bromide Cluster (HBCD) and 1,4-Dioxane, and associated documents. The purpose of the risk evaluations under the Toxic Substances Control Act (TSCA) is to determine whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. EPA is also submitting these same documents to the TSCA Science Advisory Committee on Chemicals (SACC) for peer review and is announcing that there will be a 5-day in-person meeting of the TSCA SACC to consider and review these draft risk evaluations. Preceding the in-person meeting, there will be a 3-hour preparatory virtual meeting for the panel to consider the scope and clarity of the draft charge questions for the peer reviews.

DATES: *Meetings:* The preparatory virtual meeting will be held on July 10, 2019, from 1 p.m. to approximately 4 p.m. (EDT). The 5-day in-person meeting will be held on July 29, 2019 from 1:00 p.m. to 5:30 p.m. (EDT) and July 30, 2019 to August 2, 2019 from 9:00 a.m. to approximately 5:30 p.m. (EDT).

Comments: Comments on the draft risk evaluations must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Written comments for and requests to make oral comments during the TSCA SACC meeting must be submitted on or before July 19, 2019 for consideration by the TSCA SACC. For additional instructions, see Unit II.A. and Unit II.B. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: *Webcast:* The preparatory virtual meeting will be conducted via webcast and telephone. Registration is required to participate during the preparatory virtual meeting. Please visit <https://www.epa.gov/tsca-peer-review> website for additional information including how to register. The 5-day in-person meeting may also be webcast. Please refer to the TSCA SACC website at <https://www.epa.gov/tsca-peer-review> for information on how to access the webcast. Please note that for the in-person meeting, the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the in-person meeting will continue as planned.

In-Person Meeting: The 5-day in-person meeting will be held at the Holiday Inn Rosslyn at Key Bridge, Rosslyn Ballroom, 1900 North Fort Myer Drive, Arlington, VA 22209.

Comments. Submit your comments, identified by the respective docket identification (ID) numbers for each chemical (i.e., Cyclic Aliphatic Bromide Cluster (HBCD) (EPA-HQ-OPPT-2019-0237) and 1,4-Dioxane (EPA-HQ-OPPT-2019-0238)), by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPPT Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

Requests to present oral comments and requests for special accommodations. Submit requests for special accommodations, or requests to present oral comments (*in-person or over the telephone*) to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: TSCA SACC meetings: Dr. Todd Peterson, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-6428; email address: peterston.todd@epa.gov.

Risk Evaluations: Dr. Stan Barone, Office of Pollution Prevention and Toxics (7403M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 202-564-1169; email address: barone.stan@epa.gov.

Special accommodations for the SACC meeting: For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of interest to persons who are or may be required to conduct testing and risk evaluations of chemical substances under the TSCA, 15 U.S.C. 2601 *et seq.* Since other entities may also be interested in these risk evaluations, the EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What action is the EPA taking?

EPA is announcing the availability of and seeking public comment on the draft Risk Evaluations for Cyclic Aliphatic Bromide Cluster (HBCD) and 1,4-Dioxane, and associated documents. EPA is seeking public comment on all aspects of these draft risk evaluations, including any conclusions, findings, determinations, and the submission of any additional information that might be relevant to the science underlying the risk evaluations and the outcome of the systematic review associated with HBCD and 1,4-Dioxane. This 60-day comment period on the draft risk evaluations satisfies TSCA section 6(b)(4)(H), which requires EPA to “provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation” and 40 CFR 702.49(a), which states that “EPA will publish a draft risk evaluation in the *FEDERAL REGISTER*, open a docket to facilitate receipt of public comment, and provide no less than a 60-day comment period, during which time the public may submit comment on EPA's draft risk evaluation.” In addition to any new comments on the draft risk evaluations, the public should resubmit or clearly identify any previously filed comments, modified as appropriate, that are relevant to these risk evaluations and that the submitter feels have not been addressed. EPA does not intend to respond to comments submitted prior to the release of these draft risk evaluations.

EPA is also submitting these same documents to the TSCA SACC for peer review and

announcing the meetings for the peer review panel. All comments submitted to the dockets for consideration by the TSCA SACC by the deadline identified in **DATES** will be provided to the TSCA SACC peer review panel, which will have the opportunity to consider the comments during its discussions.

C. What is the EPA's authority for taking this action?

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.” 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that direct which chemical substances must undergo evaluation, the development of criteria for manufacturer-requested evaluations, the minimum components of an EPA risk evaluation, and the timelines for public comment and completion of the risk evaluation. The law also requires that EPA operate in a manner that is consistent with the best available science and make decisions based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).

The statute identifies the minimum components EPA must include in all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) integrate and assess available information on hazards and exposure for the conditions of

use of the chemical substance, including information on specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposure. 15 U.S.C. 2605(b)(4)(F)(i)-(ii) and (iv)-(v). The risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

The statute requires that the risk evaluation process last no longer than three years, with a possible additional six-month extension. 15 U.S.C. 2605(b)(4)(G). The statute also requires that the EPA allow for no less than a 30-day public comment period on the draft risk evaluation, prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4)(H).

II. TSCA SACC Meetings

The focus of the public meeting is to peer review EPA's draft risk evaluations of Cyclic Aliphatic Bromide Cluster (HBCD) and 1,4-Dioxane. After the peer review process, EPA will consider reviewer comments and recommendations and public comments, in finalization of the risk evaluations. The draft risk evaluations contain: discussion of chemistry and physical-chemical properties; characterization of uses/sources; environmental fate and transport assessment; engineering release(s) and occupational exposure assessment; general population, consumer and environmental exposure assessment; human health hazard assessment; environmental hazard assessment; risk characterization; risk determination; and a detailed description of the systematic review process developed by the Office of Pollution Prevention and Toxics to search, screen, and evaluate scientific literature for use in the risk evaluation process.

A. How may I participate in the in-person meeting?

You may participate in the 5-day in person meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify the corresponding docket ID numbers for Cyclic Aliphatic Bromide Cluster (HBCD) (EPA-HQ-OPPT-2019-0237) and 1,4-Dioxane (EPA-HQ-OPPT-2019-0238) in the subject line on the first page of your request.

1. *Written comments.* To provide TSCA SACC the time necessary to consider and review your comments, written comments must be submitted by the date outlined in the **DATES** section and using the instructions in **ADDRESSES** and Unit II.C.

2. *Oral comments.* In order to be included on the meeting agenda, submit your request to make brief oral comments to the TSCA SACC during the in-person meeting to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before the date outlined in the **DATES** section. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment. Oral comments before TSCA SACC during the in-person meeting are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 30 copies of his or her comments and presentation for distribution to TSCA SACC at the meeting by the DFO.

3. *Seating at the meeting.* Seating at the meeting will be open and on a first-come basis.

B. How may I participate in the preparatory virtual meeting?

Registration for the July 10, 2019, preparatory virtual meeting is required. To participate by listening or making a comment during this meeting, please visit: <https://www.epa.gov/tsc-peer-review> website to register. Registration online will be confirmed by email that will include the webcast meeting link and audio teleconference information.

1. *Written comments.* Written comments for consideration during the preparatory virtual

meeting should be submitted, using the instructions in **ADDRESSES** and Unit II.C., on or before July 9, 2019.

2. *Oral comments.* Requests to make brief oral comments to the TSCA SACC during the preparatory virtual meeting should be submitted when registering online or with the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before noon on July 9, 2019. Oral comments before TSCA SACC during the preparatory webcast are limited to approximately 5 minutes due to the time constraints of this webcast.

3. *Webcast.* The preparatory virtual meeting will be webcast only, and will be open to the public. Please refer to the TSCA SACC website at <http://www.epa.gov/tsca-peer-review> for information on how to access the webcast. Registration is required.

C. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through regulations.gov or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

III. Background

A. What is EPA's risk evaluation process for existing chemicals under TSCA?

The risk evaluation process is the second step in EPA's existing chemical process under TSCA, following prioritization and before risk management. As these two chemicals are part of the first ten chemical substances undergoing risk evaluation, the chemical substances that are the subject of this announcement were designated for risk evaluation and were not required to go

through prioritization (81 FR 91927, December 19, 2016) (FRL-9956-47). The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, not consider costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out in 40 CFR part 702 and summarized on EPA's website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>. As explained in the preamble to EPA's final rule on procedures for risk evaluation (82 FR 33726, July 20, 2017) (FRL-9964-38), the specific regulatory process set out in 40 CFR part 702, subpart B will be followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

B. What is Cyclic Aliphatic Bromide Cluster (HBCD)?

The hexabromocyclodecanes (HBCD cluster) in the cyclic aliphatic bromide cluster consists of the following chemicals: Hexabromocyclododecane; 1,2,5,6,9,10-Hexabromocyclododecane; and 1,2,5,6-Tetrabromocyclooctane. HBCD is a flame retardant and is primarily used in construction materials, which may include structural insulated panels (SIPS). The building and construction industry uses expanded polystyrene foam (EPS) and extruded polystyrene foam (XPS) for thermal insulation boards and laminates for sheathing products. HBCD is also used in replacement parts for vehicles and in solder paste. Data reported for the 2016 Chemical Data Reporting period for HBCD indicate that between 1 and 10 million lb of

each chemical component were manufactured in or imported into the U.S. in 2015; however, domestic manufacture of HBCD has since ceased.

Information about the problem formulation and scope phases of the risk evaluation for this chemical is available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-cyclic-aliphatic-bromide-cluster-hbcd>.

C. What is 1,4-Dioxane?

1,4-Dioxane is used primarily as a solvent in industrial and commercial processes, such as in the manufacture of other chemicals, as a processing aid, a laboratory chemical reagent, and in adhesives and sealants. Historically, 90% of 1,4-dioxane production was used as a stabilizer in chlorinated solvents such as 1,1,1-trichloroethane (TCA). The 2016 Chemical Data Reporting data shows that there were two manufacturers producing or importing over 1 million pounds in the U.S. in 2015.

Information about the problem formulation and scope phases of the risk evaluation for this chemical is available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-14-dioxane>.

D. What is the purpose of the TSCA SACC?

The TSCA SACC was established by EPA in 2016 and operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C Appendix 2 *et seq.* The SACC supports activities under TSCA, the Pollution Prevention Act (PPA), 42 U.S.C. 13101 *et seq.*, and other applicable statutes. The TSCA SACC provides expert independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA.

The TSCA SACC is comprised of experts in: toxicology; human health and environmental risk assessment; exposure assessment; and related sciences (e.g., synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, PBPK modeling, computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability). The TSCA SACC currently consists of 24 members. When needed, the committee will be assisted in their reviews by ad hoc participants with specific expertise in the topics under consideration.

E. TSCA SACC Documents and Meeting Minutes

EPA's background paper, related supporting materials, and draft charge/questions to TSCA SACC are available on the TSCA SACC website and in the dockets for Cyclic Aliphatic Bromide Cluster (HBCD) (EPA-HQ-OPPT-2019-0237) and 1,4 Dioxane (EPA-HQ-OPPT-2019-0238). In addition, the EPA will provide additional background documents (e.g., TSCA SACC members participating in this meeting and the meeting agenda) as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available, at <http://www.regulations.gov> and the TSCA SACC website at <https://www.epa.gov/tsca-peer-review>.

TSCA SACC will prepare meeting minutes summarizing its recommendations to the EPA. The meeting minutes will be posted on the TSCA SACC website and in the relevant dockets.

Authority: 15 U.S.C. 2601 *et seq.*; 15 U.S.C. 2625 *et. seq.*; 5 U.S.C Appendix 2 *et. seq.*

Dated: June 25, 2019.

Andrew R. Wheeler,

Administrator.